Application No. 10/671,715 Docket No.: N9810.0025/P025
Amendment dated November 20, 2006

Reply to Office Action of May 19, 2006

AMENDMENTS TO THE CLAIMS

1. (Currently amended) A method of administering zolpidem or a pharmaceutically acceptable salt thereof to a mammal, comprising spraying the oral mucosa of the mammal with a propellant free buccal spray composition for transmucosal administration of zolpidem or a pharmaceutically acceptable salt thereof comprising: zolpidem or a pharmaceutically acceptable salt thereof in an amount of between 0.001 and 60 percent by weight of the total composition; and a polar solvent in an amount between 30 and 99.69 percent by weight of the total composition.

- 2. (Currently amended) The composition method of claim 1, further comprising a taste mask and/or flavoring agent in an amount of between 0.1 and 10 percent by weight of the total composition.
- 3. (Currently amended) The composition method of claim 2, wherein the polar solvent is present in an amount between 37 and 98.58 percent by weight of the total composition, the zolpidem or a pharmaceutically acceptable salt thereof is present in an amount between 0.005 and 55 percent by weight of the total composition, and the taste mask and/or flavoring agent is present in an amount between 0.5 and 8 percent by weight of the total composition.
- 4. (Currently amended) The composition method of claim 3, wherein the polar solvent is present in an amount between 60.7 and 97.06 percent by weight of the total composition, the zolpidem or a pharmaceutically acceptable salt thereof is present in an amount between 0.01 and 40 percent by weight of the total composition, and the taste mask and/or flavoring agent is present in an amount between 0.75 and 7.5 percent by weight of the total composition.

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- 5. (Currently amended) The composition method of claim 1, wherein the polar solvent is selected from the group consisting of polyethylene glycols having a molecular weight between 400 and 1000, C₂ to C₈ mono- and poly-alcohols, and C₇ to C₁₈ alcohols of linear or branched configuration.
- 6. (Currently amended) The composition <u>method</u> of claim 1, wherein the polar solvent comprises polyethylene glycol.
- 7. (Currently amended) The composition method of claim 1, wherein the polar solvent comprises ethanol.
- 8. (Currently amended) The composition method of claim 2, wherein the flavoring agent is selected from the group consisting of synthetic or natural oil of peppermint, oil of spearmint, citrus oil, fruit flavors, sweeteners, and mixtures thereof.
 - 9. (Canceled).
- 10. (Currently amended) The method of claim [[9]]1, wherein the amount of the spray is predetermined.

Claims 11-21 (Canceled).

22. (Currently amended) A method of administering zolpidem or a pharmaceutically acceptable salt thereof to a mammal, comprising spraying the oral mucosa of the mammal with a propellant free buccal spray composition for transmucosal administration of zolpidem or a pharmaceutically acceptable salt thereof comprising: zolpidem or a pharmaceutically acceptable salt thereof in an amount between 0.005 and 55 percent by weight of the total composition; and a non-polar solvent in an amount between 30 and 99.69 percent by weight of the total composition.

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23. (Currently amended) The composition method of claim 22, further comprising a taste mask and/or flavoring agent in an amount between 0.1 and 10

percent by weight of the total composition.

24. (Currently amended) The composition method of claim 23, wherein the

flavoring agent is selected from the group consisting of synthetic or natural oil of

peppermint, oil of spearmint, citrus oil, fruit flavors, sweeteners, and mixtures thereof.

25. (Currently amended) The composition method of claim 22, wherein the

solvent is selected from the group consisting of (C2-C24) fatty acid (C2-C6) esters, C7-C18

hydrocarbons of linear or branched configuration, C2-C6 alkanoyl esters, and

triglycerides of C2-C6 carboxylic acids.

26. (Currently amended) The composition method of claim 25, wherein the

solvent is a triglyceride.

27. (Canceled).

28. (Currently amended) The method of claim [[27]]22, wherein the amount of

the spray is predetermined.

Claims 29-39 (Canceled).

40. (Currently amended) A method of administering zolpidem or a

pharmaceutically acceptable salt thereof to a mammal, comprising spraying the oral

mucosa of the mammal with a buccal spray composition for transmucosal

administration of zolpidem or a pharmaceutically acceptable salt-thereof-comprising:

zolpidem or a pharmaceutically acceptable salt thereof in an amount between 0.2 and

10 percent by weight of the total composition; and a polar solvent comprising

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propylene glycol and ethanol in an amount between 50 and 99 percent by weight of the total composition.

- 41. (Currently amended) A method of administering zolpidem or a pharmaceutically acceptable salt thereof to a mammal, comprising spraying the oral mucosa of the mammal with a propellant free buccal spray composition for transmucosal administration of zolpidem or a pharmaceutically acceptable salt thereof comprising: zolpidem or a pharmaceutically acceptable salt thereof in an amount of between 0.001 and 60 percent by weight of the total composition; and a mixture of a polar solvent and a non-polar solvent in an amount of between 30 and 99.69 percent by weight of the total composition, wherein the ratio of the polar solvent to the non-polar solvent ranges from 1:99 to 99:1.
- 42. (Currently amended) The composition method of claim 40, further comprising a taste mask and/or flavoring agent in an amount of between 0.1 and 10 percent by weight of the total composition.
- 43. (Currently amended) The composition method of claim 42, wherein the polar solvent is present in an amount between 37 and 98.58 percent by weight of the total composition, the zolpidem or a pharmaceutically acceptable salt thereof is present in an amount between 0.005 and 55 percent by weight of the total composition, and the taste mask and/or flavoring agent is present in an amount between 0.5 and 8 percent by weight of the total composition.
- 44. (Currently amended) The composition method of claim 43, wherein the polar solvent is present in an amount between 60.7 and 97.06 percent by weight of the total composition, the zolpidem or a pharmaceutically acceptable salt thereof is present in an amount between 0.01 and 40 percent by weight of the total composition, and the

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taste mask and/or flavoring agent is present in an amount between 0.75 and 7.5 percent

by weight of the total composition.

45. (Currently amended) The composition method of claim 41, wherein the

polar solvent is selected from the group consisting of polyethylene glycols having a

molecular weight between 400 and 1000, C2 to C8 mono- and poly-alcohols, and C7 to

C₁₈ alcohols of linear or branched configuration and the non-polar solvent is selected

from the group consisting of (C2-C24) fatty acid (C2-C6) esters, C7-C18 hydrocarbons of

linear or branched configuration, C2-C6 alkanoyl esters, and triglycerides of C2-C6

carboxylic acids.

46. (Currently amended) The composition method of claim 42, wherein the

flavoring agent is selected from the group consisting of synthetic or natural oil of

peppermint, oil of spearmint, citrus oil, fruit flavors, sweeteners, and mixtures thereof.

47. (Canceled).

48. (Currently amended) The method of claim [[47]]41, wherein the amount of

the spray is predetermined.

Claims 49-56 (Canceled).

57. (Currently amended) [[A]]The method of claim 1, further comprising

treating insomnia in a patient, comprising spraying the oral mucosa of the patient with

a therapeutically effective amount of the buccal spray-of claim 1.

58. (Canceled).

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59. (Currently amended) [[A]]<u>The</u> method of <u>claim 22</u>, <u>further comprising</u> treating insomnia in a patient, comprising spraying the oral mucosa of the patient with

a therapeutically effective amount of the buccal spray-of claim 22.

60. (Canceled).

61. (Currently amended) [[A]]The method of claim 41, further comprising

treating insomnia in a patient, comprising spraying the oral mucosa of the patient with

a therapeutically effective amount of the buccal spray of claim 41.

62. (Canceled).

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